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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,325	06/04/2001	Stuart A. Fine	AKT-053.02	9479

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FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,325

Applicant(s)

FINE ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-133 is/are pending in the application.
- 4a) Of the above claim(s) 97,98,100,101,104-114 and 117-133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99,102,103,115 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

CLAIMS 97-133 ARE ARE PRESENTED FOR
EXAMINATION

DETAILED ACTION

Applicants' claim 99 is missing from the newly submitted claims. The claims have been renumbered from claim 100 to 134 as claims 99-133 under 37 CFR 1.126. The present action is directed to the renumbered claims. Applicants are advised to renumber their claims.

Election/Restrictions

Applicant's election with traverse of a sulfonylurea as the anti-diabetic agent and vanadium as the bioavailable source in Paper No. 9 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner in the examination of the subject application. This is not found persuasive because the claims are drawn to a vast number of combinations of anti-diabetic agents and bioavailable sources such as vanadium and chromium, claims 97 and 98, which read only on bioavailable sources; b) vanadium and thiazolidinediones; c) vanadium and sulfonylureas; and d) vanadium and benzoic acid derivatives and c) vanadium and alpha-glucosidase inhibitors. The anti-diabetic agents in b) to e) can also be combined with chromium as the bioavailable source. The searches to be properly performed would involve a search of subclasses throughout classes 514 and 424. It would also be a burden on the examiner since the pharmaceutical journals need to be searched.

Art Unit: 1617

Therefore, contrary to the applicants' assertion, claims 97-98, renumbered claims 100, 101, 104-114 and 117-133 are not within the scope of applicants' election since they read on claims drawn to the combination of vanadium and chromium or vanadium and/or chromium with an anti-diabetic agent other than a sulfonylurea.

The requirement is still deemed proper and is therefore made FINAL.

In view of the above, claims 97, 98 and 100, 101, 104-114 -133 are withdrawn from consideration.

Claims 99, 102, 103, 115 and 116 are drawn to and read on the elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 100, 102, 103, 113, 115 and 116 are rejected under 35

U.S.C. 102(a) as being anticipated by Gutierrez et al. (5,885,980).

Gutierrez et al. disclose and teach in the abstract, at column 1, lines 35 to column 2, line 34, claim 2, lines 46-57, column 3, lines 30-50 and column 4, lines 6-15 the use of vanadium compounds (vanadyl sulfate) combined with a sulfonylurea to treat diabetes (claims 100, 102, 103, 113, 115 and 116).

Art Unit: 1617

At column 4, lines 56-65 it is taught that the combination is administered for more than 30 days (claim 116) and the amount of agents are within the range of of claim 115 of more than 10 mgs. The sulfonylurea, glybride (claim 103) is taught in the abstract.

The beneficial effects of the combination (claim 115) are taught at Examples 2 and 3 of the cited reference.

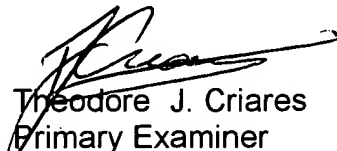
None of the claims are allowed.

Applicants are requested to review their patent portfolios to avoid double patenting.
Any inquiry concerning this communication or earlier

communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

Application/Control Number: 09/787,325

Page 5

Art Unit: 1617

tjc

June 2, 2003